

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Dulak & Clayman

Serial No.:

Filed: Herewith

Title: URETERAL ACCESS
SHEATH

Examiner:

Group Art Unit:

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Prior to an Office Action on the merits, this amendment is being filed in connection with the above-identified divisional application.

IN THE SPECIFICATION

Please add the following minor heading and paragraph after the major heading "Background of the Invention."

--Cross-Reference to Related Applications

This is a provisional application claiming priority of Patent Application Serial No. 09/303,485 filed on April 30, 1999 and entitled Ureteral Access Sheath.--

Please substitute the following paragraph for the paragraph beginning on page 5, line 29:

--In operation, as the surgical instrument, such as the obturator 12, is inserted into the handle 23, it produces a force F_1 (illustrated by arrow 54) in the distal direction. This force is opposed by the fingers 50 and 52, which engage the distally-facing surface and apply opposing forces F_2 and F_3 (represented by arrows 56 and 58). In this manner, the fingers 50 and 52 can maintain the sheath 10 generally stationary even when the obturator 12 is being inserted. It will also be noted that with the user's hand in the natural position, it tends to form a barrier which prevents any instrumentation from extending exteriorly beyond the handle 23 into contact with ureteral tissue 60. As shown in Figure 5, the urethra has a first diameter. The tube 14 has a second diameter that is less than the first diameter of the urethra while the handle 23 has a third diameter greater than the first diameter of the urethra.--

Please substitute the following paragraph for the paragraph beginning on page 6, line 7:

- - Although the embodiment of Figure 5 is particularly adapted to facilitate insertion of a surgical instrument, such as the obturator 12, it will be appreciated that removal of the instrument also creates withdrawal forces on the sheath 10. A further embodiment of the handle which can easily accommodate not only insertion forces but also withdrawal forces, is illustrated in Figure 6. In this embodiment, a handle 61 is similar to the handle 23, except that the outer, distally-facing surface 43, as shown in Figure 4, is curved distally outwardly to form a proximally-facing outer surface 63. In this case, the two surfaces 41 and 63 form a continuous surface which defines an annular recess sized and configured to receive the fingers 50 and 52. - -

Please substitute the following paragraph for the paragraph beginning on page 6, line 23:

- - Figures 7-9 illustrate a further embodiment involving a handle, such as the handles 23 or 61, which is moveable relative to the tube 14 of the sheath 10. This embodiment is particularly desirable as it permits the tube 14 to be cut in situ, at the operative site, to a preferred length. With a sheath of this type, only a single access device need be present at the operative site. Multiple sheaths having different lengths are not required to be present in order to have a sheath of the desired length. As illustrated in Figure 7, this embodiment of the sheath 10 includes the tube 14 which is slidably engageable by a handle assembly 72 that includes a sleeve 74 and a funnel 76. The sleeve 74 is formed as a cylinder 77 having an interior bore 78 and external threads 81. An elastomeric element or washer 83 is disposed within the bore 78 and is provided with an axial lumen 84 appropriately sized to receive the tube 14. - -

Please substitute the following paragraph for the paragraph beginning on page 7, line 8:

- - In operation, the funnel 76 is moved axially over the sleeve 74 and the internal threads 90 are screwed onto the external threads 81. Further rotation of the funnel 76 relative to the sleeve 74, causes the distal surface 92 of the inner cylinder or nut 87 to axially compress the elastomeric element 83. This compression causes the element 83 to expand inwardly decreasing the diameter of its lumen 84 and thereby increasing the frictional engagement of the handle assembly 72 relative to the tube 14. - -

Please substitute the following paragraph for the paragraph beginning on page 7, line 19: .

- - In another embodiment illustrated in Figure 10, a movable handle assembly 96 includes a funnel 98 similar to the handle 23. It also includes a cylinder 99 which extends distally with thin portions 101 which have a reduced diameter. A separate finger clamp 102 includes a cylinder 104 which has a diameter which is dependent upon operation of finger tabs 103 and 105. When these tabs 103 and 105 are compressed, the cylinder 104 has a relatively large diameter. When the tabs 103 and 105 are not compressed, the cylinder 104 is biased toward a reduced diameter. This finger clamp 102 is intended to be operatively disposed over the thin portions 101 of the cylinder 99, as illustrated in Figure 11. In this operative position, the entire handle assembly 96 can be moved along the tube 14 by compressing the finger tabs 103 and 105 of the clamp 102. The tube 14 can then be cut, for example, with scissors 106, to any desired length. Compressing the finger tabs 103 and 105 will permit the handle assembly 96 to be moved to a distal position, as illustrated in Figure 11, where the tabs 103 and 105 can be released to compress the thin positions 101 and maintain the handle assembly 96 in a fixed relationship with the tube 14. - -

IN THE CLAIMS

Please cancel Claims 1-9, 11 and 15-20 without prejudice.

Please substitute the following claims for the pending claims of the same number:

1 10. (Amended) A method for inserting a medical instrument into a urethra,
2 comprising the steps of:

3 providing a urethral access device having an elongate tube with a lumen
4 extending along an axis between a proximal end and a distal end, and a handle at the
5 proximal end of the tube;

6 configuring the handle with a distally-facing, concave surface and proximally-
7 facing surface, the distally-facing surface being sized and configured to receive two
8 adjacent fingers of a user's hand;

9 inserting the distal end of the tube into the urethra to an operating position in
10 order to provide access for the medical instrument;

11 moving the medical instrument distally into the proximal end of the lumen of the
12 tube and through the lumen of the tube into the urethra;

13 during the moving step creating a distal force on the urethral access device; and

14 applying a proximal force on the distally-facing surface of the handle to oppose
15 the distal force and maintain the access device in the operative position.

1 12. (Amended) The method recited in Claim 10 wherein the configuring step
2 further comprises the step of:

3 forming the proximally-facing surface with a convex configuration.

1 14. (Amended) The method recited in Claim 13 further comprising the steps of:
2 facilitating a generally fixed relationship between the handle and the tube at the
3 predetermined position.

1 21. (Amended) A method for providing a surgical access device with a desirable
2 length, comprising the steps of:

3 providing an elongate tube having a working channel and a handle assembly
4 having an engagement apparatus adapted to fit over the tube, the handle having a
5 movable relationship with the tube when the engagement apparatus is in a first state
6 and a fixed relationship with the tube when the engagement apparatus is in a second
7 state;

8 placing the engagement apparatus in the first state;
9 removing a portion of the elongate tube to shorten the length of the tube
10 generally to the desired length;

11 moving the handle to a predetermined location along the tube; and
12 placing the engagement apparatus in the second state to fix the handle to the
13 tube at the predetermined location and provide the access device with the desired
14 length.

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1 22. (Amended) The method recited in Claim 21 wherein the providing step
2 includes the step of providing the engagement apparatus with an elastomeric washer
3 sized and configured to fit around the tube; and
4 the second placing step includes the step of compressing the washer around the
5 tube.

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Please add the following claims:

1 23. The method recited in Claim 14 wherein the facilitating step comprises the
2 steps of:

3 mounting a sleeve with an elastomeric washer on the tube; and
4 screwing the handle onto the sleeve.

1 24. The method recited in Claim 14 wherein the facilitating step comprises the
2 steps of:

3 forming the handle with a distal cylinder having a thin portion with a reduced
4 diameter; and
5 clamping an engagement apparatus onto the thin portion of the distal cylinder.

6 25. The method recited in Claim 21, wherein the handle comprises a distal
7 cylinder and the engagement apparatus comprises a clamp compressible between a
8 large diameter and a small diameter, and wherein:

9 the step of placing the engagement apparatus in the first state comprises moving
10 the clamp to facilitate the large diameter; and

11 the step of placing the engagement apparatus in the second state comprises
12 moving the clamp to facilitate the small diameter.

1 26. A method for assembling a medical access device, comprising the steps
2 of:

3 providing an elongate tube having a working channel;

4 forming a handle assembly with a distally extending cylinder configured to be
5 disposed around the elongate tube;
6 providing a clamp that is adjustable between a first state having a large diameter
7 state and a second state having a small diameter;
8 disposing the clamp over the distally extending cylinder;
9 moving the handle assembly relative to the tube with clamp in the first state; and
10 fixing the handle assembly onto the tube with the clamp in the second state.

1 27. The method of Claim 26, wherein:

2 the step of providing a clamp comprises the step of forming the clamp with finger
3 tabs;

4 the step of moving the handle assembly comprises the step of compressing the
5 finger tabs; and

6 the step of fixing the handle assembly onto the tube comprises the step of
7 releasing the finger tabs.

1 28. A method for assembling a medical access device, comprising the steps
2 of:

3 providing an elongate tube having a working channel;

4 providing an elastomeric washer with a lumen sized to receive the elongate tube;

5 providing a sleeve configured to mount the elongate tube;

6 disposing the elastomeric washer within the sleeve;

7 mounting the sleeve and the elastomeric washer onto the elongate tube;

8 forming a handle assembly with a nut configured to compress the elastomeric
9 washer; and
10 coupling the handle assembly to the sleeve such that the nut compresses the
11 elastomeric washer.

1 29. The method recited in Claim 28, wherein the step of forming a handle
2 assembly with a nut comprises the step of forming the nut as a cylinder.

1 30. The method recited in Claim 28, wherein:
2 the step of providing a sleeve comprises the step of providing the sleeve with
3 external threads;
4 the step of forming a handle assembly with a nut comprises the step of providing
5 the handle assembly with internal threads configured to mate with the external threads
6 of the sleeve; and
7 the step of coupling the handle assembly to the sleeve comprises the step of
8 screwing the handle assembly onto the sleeve.

1 31. The method recited in Claim 28, wherein the step of coupling the handle
2 assembly to the sleeve such that the nut compresses the washer comprises the step of
3 decreasing a diameter of the lumen.

REMARKS

Prior to an action on the merits, this Preliminary Amendment is being filed concurrently with the filing of the above-identified divisional application.

DRAWINGS

Applicants have amended the specification to clarify that the inner cylinder 87 shown in Figure 8 is the nut that compresses the elastomeric washer 83.

Furthermore, in Figure 5, numeral 14 has been included to indicate the tube. In Figure 6, numeral 61 has been included to indicate the second handle. No new matter has been added.


SPECIFICATION

Applicants have made minor changes to correct typographical and grammatical errors and to clarify what has been previously disclosed. No new matter has been added.

SUMMARY

Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

Respectfully Submitted,



Richard L. Myers
Registration No. 26,490

22872 Avenida Empresa
Rancho Santa Margarita, California 92688
Telephone (949) 713-8000
Facsimile (949) 713-8206

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this case, the two surfaces 41 and 63 form a continuous surface which defines an annular recess sized and configured to receive the fingers 50 and 52. - -

Paragraph beginning on page 6, line 23 has been amended as follows:

- - Figures 7-9 ~~illustrated~~ illustrate a further embodiment involving a handle, such as the handles 23 or 61, which is moveable relative to the tube 14 of the sheath 10. This embodiment is particularly desirable as it permits the tube 14 to be cut in situ, at the operative site, to a preferred length. With a sheath of this type, only a single access device need be present at the operative site. Multiple sheaths having different lengths are not required to be present in order to have a sheath of the desired length. As illustrated in Figure 7, this embodiment of the sheath 10 includes the tube 14 which is slidably engageable by a handle assembly 72 that includes a sleeve 74 and a funnel 76. The sleeve 74 is formed as a cylinder 77 having an interior bore 78 and external threads 81. As elastomeric element or washer 83 is disposed within the bore 78 and is provided with an axial lumen 84 appropriately sized to receive the tube 14. - -

Paragraph beginning on page 7, line 8 has been amended as follows:

- - In operation, the funnel 76 is moved axially over the sleeve 74 and the internal threads 90 are screwed onto the external threads 81. Further rotation of the funnel 76 relative to the sleeve 74, causes the distal surface 92 of the inner cylinder or nut 87 to axially compress the elastomeric element 83. This compression causes the element 83 to expand inwardly decreasing the diameter of its lumen 84 and thereby increasing the frictional engagement of the handle assembly 72 relative to the tube 14. - -

Paragraph beginning on page 7, line 19 has been amended as follows:

- - In another embodiment illustrated in Figure 10, a movable handle assembly 96 includes a funnel 98 similar to the handle 23. It also includes a cylinder 99 which extends distally ~~within~~ with thin portions 101 which have a reduced diameter. A separate finger clamp 102 includes a cylinder 104 which has a diameter which is dependent upon operation of finger tabs 103 and 105. When these tabs 103 and 105 are compressed, the cylinder 104 has a relatively large diameter. When the tabs 103 and 105 are not compressed, the cylinder 104 is biased toward a reduced diameter. This finger clamp 102 is intended to be operatively disposed over the thin portions 101 of the cylinder 99, as illustrated in Figure 11. In this operative position, the entire handle assembly 96 can be moved along the tube 14 by compressing the finger tabs 103 and 105 of the clamp 102. The tube 14 can then be cut, for example, with scissors 106, to any desired length. Compressing the finger tabs 103 and 105 will permit the handle assembly 96 to be moved to a distal position, as illustrated in Figure 11, where the tabs 103 and 105 can be released to compress the thin positions 101 and maintain the handle assembly 96 in a fixed relationship with the tube 14. - -

In the Claims:

The claims have been amended as follows.

Claims 1-9, 11 and 15-20 have been canceled.

10. (Amended) A method for inserting a medical instrument into a urethra, comprising the steps of:

providing a urethral access device having an elongate tube with a lumen extending along an axis between a proximal end and a distal end, and a handle at the proximal end of the tube;

configuring the handle with a distally-facing, concave surface and proximally-facing surface, the distally-facing surface being sized and configured to receive two adjacent fingers of a user's hand;

inserting the distal end of the tube into the urethra to an operating position in order to provide access for the medical ~~device~~instrument;

moving the medical ~~device~~instrument distally into the proximal end of the lumen of the tube and through the lumen of the tube into the urethra;

during the moving step creating a distal force on the urethral access ~~sheath~~device; and

applying a proximal force on the distally-facing surface of the handle to oppose the distal force and maintain the access ~~sheath~~device in the operative position.

12. (Amended) The method recited in Claim ~~11~~10 wherein the configuring step further comprises the step of:

forming the proximally-facing surface with a convex configuration.

14. (Amended) The method recited in Claim ~~14~~13 further comprising the steps of:

facilitating a generally fixed relationship between the handle and the tube at the predetermined position.

21. (Amended) A method for providing a surgical access device with a desirable length, comprising the steps of:

providing an elongate tube having a working channel and a handle assembly having an engagement apparatus adapted to fit over the tube, the handle having a movable relationship with the tube when the engagement apparatus is in a first state and a fixed relationship with the tube when the engagement apparatus is in a second state;

placing the engagement apparatus in the first state;

removing a portion of the elongate tube to shorten the length of the tube generally to the desired length;

moving the handle to a predetermined location along the tube; and

placing the engagement apparatus in the second state to fix the handle to the tube at the predetermined location and provide the access device with the desired length.

22. (Amended) The method recited in Claim 21 wherein the ~~second~~ providing step includes the step of providing the engagement apparatus with an elastomeric washer sized and configured to fit around the tube; and

the second placing step includes the step of compressing the washer around the tube.

Claims 23-31 have been added.

